Endovascular Intervention

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TCT-511

Percutaneous Transluminal Angioplasty of the Subclavian Arteries. Long-Term Follow up.

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Background: To review feasibility, safety and long-term results of subclavian artery angioplasty.
Methods: 407 patients (males: 245, mean age: 66.1 ± 12 y) underwent percutaneous treatment for subclavian artery (SA) occlusive disease (stenosis: 295, occlusion: 112). Left: 312, Right: 95, Innominate Artery: 28. Etiology: atheromatous: 397, others: 10 (Takayasu: 6) Mean % stenosis 83.4 +/- 7.8. Mean lesion length: 23.9 +/- 8.7 mm Indications for treatment were upper limb ischemia (ULI) (n=177) Vertebrobasilar insufficiency (VBI) (n=157), associated VBI and ULI (n=123), coronary steal syndrome (n=20) asymptomatic patients with severe coronary disease (n=73) 39 patients had associated Vertebral Artery stenosis, 81 carotid stenoses. 337 prevertebral lesion, 45 post vertebral, both 25. Access: femoral (n=287), brachial (n=81), both (n=39). "Pull through technique": 8 cases. An isolated balloon angioplasty was performed in 59 cases and 348 stents were implanted (balloon expandable: 276, self expandable: 72).
Results: Technical success was obtained in 387 lesions (95 %) 100% for stenoses. Only 92 occlusions were recanalized (82 %). Four periprocedural events occurred (1.2 %), 1 major (fatal stroke), 1 T.I.A., 2 arterial thromboses. During the follow-up (mean follow-up: 75.7 months ± 38.5), we had 40 restenoses (10 %). 13 occurred following angioplasty alone (18.8 %) and 27 following angioplasty and stent implantation (7.8 %) ($P<0.01$). 10 were treated by new angioplasty alone, 30 by repeat stent implantation. Primary (PI) and secondary (PII) patencies on an intention to treat basis at 10-year follow-up were 80.2 % and 86.5 % respectively. In patients without initial stent placement, the rates were 67.5 % and 75.5 % while in those with stents, the rates rose to 91.5 % and 98.2 % ($P < 0.01$). PI for all recanalized lesions were 85.8 %, 79.1 % without stent, 91.8 % with stent ($P < 0.04$) and PII 92.8 %, 88.5 %, 98.1% respectively ($P < 0.02$).
Conclusions: P.T.A. is currently the treatment of choice for subclavian artery lesions. It is a safe and effective procedure associated with low risks and good long-term results. Stents seem to limit the restenosis rate and improve long-term results.

TCT-512

RENAL ANGIOPLASTY AND STENTING. LIMITATIONS. ROLE OF EMBOLIC PROTECTION DEVICES

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Background: Despite good immediate and long-term results, post procedural deterioration of the renal function (RF) may occur after Renal Artery Angioplasty and Stenting (RAAS) in 20-40 % of the patients, which limits the immediate benefits of the technique. Atheroembolism seems to play an important role. We evaluate feasibility and safety of RAAS utilizing a distal protection device (DPD) to reduce the risk of atheroembolism and avoid deteriorations of the RF.
Methods: 171 RAAS performed under DPD in 151 hypertensive patients (M:102). Mean age: 65.2 ± 10.8 yrs with atherosclerotic renal artery stenosis (20 bilateral). 11 pts had solitary kidneys, 62 renal insufficiencies. We used occlusion balloon (n = 46) or filters (n = 125). We recently experimented and treated 12 patients with a new filter the Fibernet (Lumen Biomedical Plymouth MN) which can capture particles of 40µ without compromising the flow. Generated debris removed and analyzed. Blood pressure and serum creatinine levels followed. Techniques of RAAS under protection, limitations will be discussed.
Results: Immediate technical success: 100 %. Visible debris aspirated with Percusurge from all patients. Mean particle number: 98.1 ± 60.00. Mean diameter: 201.2 ± 76µ (38-6206). With current filters debris were removed in 80 % of the cases. With the Fibernet visible debris were removed in all cases. Mean debris surface area: 121mm^2. Mean number of particles 28-60µ : 2136 ± 776, >60µ. We observed one acute RF deterioration. Mean follow-up: 32.2 ± 17 months. Mean creatinine level remains constant during follow-up. At 6 months (131 patients) 95 patients stabilized, 35 with baseline renal insufficiency improved and we had only one RF deterioration (1 %) in a patient with moderate renal insufficiency. At 2 years (105 patients) 73 stabilized, 28 improved and we only had 4 RF deterioration (4 %).
Conclusions: This study demonstrates the feasibility and safety of DPD during renal interventions to protect against atheroembolism and seems to avoid RF deterioration after the procedure and in the long-term. Indications will be discussed. Improvements in DPD for renal stenting are mandatory. Randomized studies are awaited.

TCT-513

RENAL ARTERY ANEURYSMS. FIRST HUMAN TREATMENT WITH THE MULTILAYER FLOW MODULATOR

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Background: Renal Artery Aneurysms (RAAs) can be surgically treated but due to high risk, endovascular procedures have been proposed (coils, graft…). All these techniques have some drawbacks, potential complications and contraindications. We propose a new technique: the Multilayer Flow Modulator (MFM*), a self expandable.
Methods: This MFM* is a 3D braided tube made of several interconnected layers without any covering. Our earliest tests, in vitro (theoretical simulation computerized Fluid dynamics, Molecular Modelization) & in vivo. demonstrate that this MFM* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions.. A saccular aneurysm (A.) without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. In fusiform A. the flow is laminated, the vortexes eliminated, eliminating the risk of rupture. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches and increases the flow in them, allowing the possibility to cover any artery without compromising the flow.
Results: 8 RAAs (right:5, left: 3) in 8 pts (male: 3) mean age 58 y. treated with MFM* 6 pts had atheromatous disease, 2 a fibromuscular dysplasia. One pt had a solitary kidney. All these pts had hypertension. 10 MFM*(Ø: 5 to 6 mm, length 30 to 60 mm) loaded in a 6 F sheath implanted by femoral approach through 8 F guiding catheter. These stents covered major renal branches without compromising the flow. Technical success: 100%. No complications. Immediately: important reduction of the velocities inside the aneurismal sac. 6 to 36 month follow up will be presented. All aneurysms thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. All the side branches remain patent.
Conclusions: The MFM* is a new technique which seems promising to treat RAAs. Collateral branches can be covered without compromising the flow and risk of renal infarction. It is a safe procedure with a very low complications rate. Larger study is ongoing.

TCT-514

The Multilayer Flow Modulator Stent for the Treatment of Popliteal Aneurysm.

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Background: Popliteal Artery Aneurysms (PA) are traditionally treated surgically. Endovascular procedures with implantation of stent grafts or covered stents have been proposed as an alternative to surgery. Results are encouraging but some problems remain (aneurysm rupture, endoleaks, collateral branch thrombosis…). We used a new concept of stent, the Multilayer Flow Modulator (MFM*) to treat aneurysms and try to avoid some drawbacks encountered with endografts.
Methods: This MFM* is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest tests in vitro (theorical simulation, computerized Fluid dynamics, Molecular Modelization) and in vivo demonstrate that this MFM* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM* preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels …).
Results: 5 PA were treated with the MFM* (male: 5, mean age: 65 y.) 9 stents (Ø6 to 8 mm, length 40 to 120 mm) were implanted by percutaneous ipsilateral femoral approach through 8F sheath. Technical success in all patients. All aneurysm thrombosed. Mid-term follow up will be presented. No stent fracture. This MFM* seems well indicated for this popliteal location.
Conclusions: A new concept of stent, the MFM* is developed to treat aneurysm. It opens a new approach to treat peripheral aneurysms avoiding most of the